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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,277	08/22/2000	M. Bud Nelson	B-28	8660
7590	12/06/2001		EXAMINER	
M Bud Nelson BioCrystal Ltd 575 McCorkle Boulevard Westerville, OH 43082-8888			SAUNDERS, DAVID A	
		ART UNIT	PAPER NUMBER	
		1644		
		DATE MAILED: 12/06/2001		
				3

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N 643,277	Applicant(s) NELSON et al
	Examiner SAUNDERS	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

#### P r i o r i t y Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disp sition of Claims

- Claim(s) 1-45 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) \_\_\_\_\_ is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) 1-45 are subject to restriction or election requirement.

#### Applicati n Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- Th specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Pri ority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

#### Attachment(s)

- |                                                                                            |                                                                         |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| <input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ | <input type="checkbox"/> Interview Summary, PTO-413                     |
| <input type="checkbox"/> Notice of Reference(s) Cited, PTO-892                             | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Revi w, PTO-948           | <input type="checkbox"/> Other _____                                    |

#### Office Acti n Summary

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to kits for testing for MS and pro-MS, classified in class 435, subclass 7.1+ and 975.
- II. Claims 10-17, 20-28 and 31-40, drawn to assay methods for sialocomplexes in sample aliquots, classified in class 435, subclass 7.1+ and class 436, subclass 501+.
- III. Claims 18-19, 29-30 and 41-42, drawn to indicators, classified in class 435, subclass 7.1+ and 967.
- IV. Claims 43-44, drawn to a separation method for removing sialocomplexes, classified in class 424, subclass 140.1 and class 536, subclass 127.
- V. Claim 45, drawn to sialocomplexes, classified in class 536, subclass 17.2+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product has other uses. For example the components of the kits could be used to stain tissue sections (e.g. as in immunofluorescent staining) or cells (e.g. as in FACS), rather than to test for sialocomplexes in a sample aliquot.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

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made by another and materially different process (MPEP § 806.05(f)). In the instant case the indicator product can be made by any immuno/specific binding assay for anything (e.g. typically any ELISA method produces an indicator as a colored reaction product of an enzyme reaction).

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by other methods (e.g. fractionation of blood plasma/serum by chromatography and/or gel filtration).

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the kit of Group inventions I would not be used in the separation process of Group IV.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the indicator of Group III would not be used in the separation process of Group IV.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups II and IV are methods employing different reagents, in different steps, using a different apparatus. The goal of each method is different.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

Claims 1-17, 20-28 and 31-40 are generic to a plurality of disclosed patentably distinct species comprising the Markush Group of affinity ligand combinations, recited in each of claims 8, 28 and 40. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 44 is generic to a plurality of disclosed patentably distinct species comprising numerous distinct glycolipids (e.g. a few examples are shown at pages 8-9) complexed with numerous distinct binding ligands (e.g. antibodies, lectins). Applicant is required to elect one species comprising a particular glycolipid complexed with a particular binding ligand. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Fri., 8:15 am-4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS  
December 5, 2001

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 1644